

Meeting Minutes			
Division:	Iowa Medicaid Enterprise Quality Improvement Organization (QIO)		
Meeting Title:	Clinical Advisory Committee (CAC)		
Facilitator:	Bill Jagiello, D.O.		
Location:	Lucas building, 321 E. 12 th St., Des Moines, 5 th Floor, Rm 517/518		
Date:	October 18, 2019	Time:	1:00 p.m. – 4:00 p.m.

Meeting Objectives
<p>The purpose of the CAC is to increase the efficiency, quality and effectiveness of the Medicaid healthcare system. The CAC provides a process for physician and other health care provider contributions to promote quality care, member safety, cost effectiveness and positive physician and provider relations through discussion about Medicaid benefits and healthcare services.</p> <p>The CAC is charged with recommending clinically appropriate healthcare utilization management and coverage decision to the Department of Human Services (DHS) for the Iowa Medicaid program.</p>

Meeting Participants	
Name	Organization
Bill Jagiello, D.O.	IME
Mark Randleman, D.O.	IME
Dr. Nick Galioto- Family Practice	
Dr. Dennis Zachary- Family Practice	
Dr. Kathy Lange- Family Practice	
Dr. Andrea Silvers- Family Practice	
Dr. Alex Hubbell- Family Practice	
Clarice Blanchard, PA-C - Family Practice/Emergency Medicine	
Dr. Daniel Wright- Pediatrician	
Dr. Angela Kloepfer	Amerigroup
Tami Sova	Biogen
Tami Lichtenberg	IME
Barb Cox	IME
Shelley Horak	IME
Cassie Reece	IME
Becky Carter	IME
Jennifer Ober	IME

Paula Motsinger	IME
Teri Stolte	IME
Dr. Sadia Ashraf Benson- On the phone	Iowa Total Care
Sherry Buske, ARNP- On the phone	

Agenda Topics	Responsible Party
Introductions/Announcements- Thank you to Dr. Wright for his 6 years of serving on CAC.	Dr. Jagiello
Approval of Minutes from August meeting- approved.	Dr. Jagiello
Old Business	Dr. Jagiello
New Business	Dr. Jagiello
Public Comment Period	Guests
Criteria Review	Dr. Jagiello
Upcoming Meetings Jan. 17, 2020 April 17, 2020 July 17, 2020 Oct. 16, 2020	Dr. Jagiello
Adjournment	Dr. Jagiello

Follow Up Items	Responsible Party

Minutes:

Old Business:

Old Business-

1. Maternal Health Task Force- Dr. Jagiello- This group was established by the legislature in 1989 to respond to an annual report on Medicaid maternal outcomes. The purpose of that group was to look for things that were actionable and implement them. We reaffirmed goals. Major initiative going on in Iowa, we attended an OB summit regarding this topic, maternal mortality is rising in Iowa as it is across the United States. The US currently ranks below 3rd world countries on rates of maternal mortality.. The IDPH- Iowa Department of Public Health and UIHC- University of Iowa Hospitals applied for and received \$10 million grant to act on lowering the maternal mortality rates within the state of Iowa. More to come on that. There was a story recently on public radio discussing diminishing access to maternal care in rural hospitals and why they are closing. Medicaid reimbursement is one of the drivers, although there are many others such as recruiting. Taking care of all issues- including access and insurance coverage- it's going to be a complicated task but certainly worth pursuing. Dr. Kloepper- It was very eye opening. Iowa's maternal mortality rate is lower than the national average but it is going up. Looking at the Medicaid population and the disparities in the maternal morbidity complications are higher in the Medicaid population than in private pay and there should be no difference between two. It's encouraging that there is more energy and an effort to organize behind the topic. Even the last 2 years the mortality rate is 16% which is crazy. Dr. Hubbell- Our obstetrics program trains a lot

of residents and this is our biggest topic of discussion right now. Iowa currently ranks 50th out of 50 of obstetric providers per capita and rural hospitals are closing down their OB floors at an alarming rate. There's no access to prenatal care. Des Moines is pretty saturated. We are already having to deliver outside of normal delivery situations because of how busy we are. We're working closely with Dr. Hunter to try to find out how we are going to get care out to the rural areas. Dr. Jagiello- It has the interest of some of the representatives from the legislature, funding is available and, with Dr. Hunter's passion, I think we will see some improvements in this area. Any questions on Maternal Fetal Medicine? Obviously more to come.

2. Opioid Crisis- Dr. Jagiello- There is a slight decline of rate of deaths. It has the public spot light in recent months noting the litigation in class action law suits- rulings against Purdue Pharma and Johnson & Johnson. Hopefully money will be sent to Iowa to help lowans affected by this crisis. Dr. Randleman- The only thing I would add is that there was such a hammer dropped on opioids that doctors were cutting people off. I think the pendulum is swinging back- not the free handing out of opioids but let's be reasonable, let's not cut people off cold turkey. It's interesting because that has been causing some mental health issues, attempted suicide also. Dr. Hubbell- There was an article from the CDC last month that the recommendations 3 years ago were aggressive and they continue to stand by those but there has been a slow titration or personalization got lost in those early recommendations and we all tried to immediately decrease to their medications and it caused a lot of problems. Dr. Randleman- Some of the pressure physicians felt was that they may get caught up in a law suit. Dr. Jagiello- Or marked by the board of medicine. Dr. Randleman- Some sort of administrative or judicial punishment so physicians were scared into actions. It's a shame how much our medicine is affected by judicial pressure. Same thing with Maternal Fetal Medicine, why don't people practice in rural areas? Some programs need childcare but there is no childcare provided because of the liability risk of watching children. Dr. Hubbell- I've had a couple people this summer get cut off very quickly with a 10% 3/3/3 day taper just as the literature has supported, that's probably happened twice within the last 3-4 months from a pain management specialist. One case was related to turn over in providers, the member hadn't even met the provider yet but the provider termed them believing that the member wasn't following the rules. I'm still seeing people feel like they are being punished for being on opioids.

New Business:

1. Shelley Horak- (See handout) Quality Committee. Leadership asked Telligen QIO asked us if we would take on the planning and facilitating the quality committee. It felt like it needed a restart so we've tried to do that. We operate under the quality committee charter that was established previously. We have a few guiding documents: MCO quality assurance plan, the quality matrix, meaningful measures framework from CMS. CMS report card from the adult and child core measures, HEDIS guidance and value based purchasing. EQRO documents, the Managed Care Quality reports and HCBS reporting elements. Selected some goals: Little bit of work and planning. Goal dev strategic communication- (handout from Shelley) Identified opportunities open to the group. Identifying internal and external stake holders. Medicaid measures comparison between plans and between states. We don't turn away any issues. We are currently choosing measures. We've identified 5 categories: overall acute care, substance abuse disorder, long term care. Dr. J- any opportunity to engage this committee with your work? Paula Motsinger- LTSS with Medicaid primary care physicians are involved in the care of these individuals. CMS 4 new measures- one related to physician involvement in that care. Make sure physicians are aware and how you can be engaged as physicians. Shelley- We will regularly run progress by director and leadership. Once we establish core set of measures I'd like to share that with you and get your feedback.
2. IME update- Dr. Jagiello- I serve on a number of committees- Hawki, CAC. Maternal Health Task Force. For a committee to be viable it has to have goal or objective, it has to have engaged committee members and robust discussion, objective, action steps. You are either doing something meaningful and taking steps to make changes to meet that goal or you're not.
3. MCO Updates-
 - a. Amerigroup- Dr. Kloepper- No big changes. She is leaving and her replacement will be hired soon weeks/months.
 - b. ITC- Dr. Benson- They went live July 1. They have a population of 300,000 members, of that 23,000 is LTSS members. They have 800 employees in Iowa, mostly care management, nursing staff, UM staff, appeal staff. We just came out of our continuation of care process. Now we are just streamlining work flows. We are working on efficiency issues. We are focusing on creating

our committees, our charters, credentialing. Getting involved with community providers. We've almost filled our Chief Medical Director- which will be like a lead. We have a behavioral health psychiatrist. We are working on integrating behavioral health and medical since there is a lot of overlapping in that care.

Public Comment Period:

Tami Sova- Biogen- provided materials for Tysabri (Natalizumab). I'm just here for any questions. No questions or concerns were offered.

Criteria Review:

Dr. Jagiello- I came from an organization that if they had a list of medical policies like this they would have had 4-5 people working on it as subject matter experts, I'm not 4-5 people. My claim to fame is not to be the brightest light in the room, but finding people around me who are bright and encouraging and inviting them to do the work. I did go over this list in the few brief weeks that I've been here, I can't tell you in all honesty that I've done it justice. Especially the monoclonal antibody drugs are highly complex, my previous organization- 2 Pharm D's would have been advising on these. So even though these are going to be discussed today, as are all the policies, I'm going to create a process change. Historically I think the medical director is supposed to look at these, occasionally go out to a subject matter expert, then we bring them to you and finally they go to the medical policy staff at Iowa Medicaid for final changes and to make sure it's not in conflict with Iowa code, anything statutory or federal laws and then they get published. To me the clinicians in this room and the public should be the final step. All of that done after your review should go beforehand, including seeking Pharm D input so that they can go over the package insert and literature to make sure we get this right. I'm afraid our current process won't get this right. If policy makes a change, I want the final draft to come back before everyone at this table to make sure we get it right. Iowa has contracted with two outstanding national organizations for managed care; they have their own subject matter experts and their own policies. Sometimes those policies don't line up. I've learned a new word since I've joined Iowa Medicaid- "provider abrasion"- why doesn't the MCO policy line up with Fee For Service? And they should, as close as we are able. Before we create a new medical policy or change a policy, I want to do a side-by-side comparison to see if we can get them as congruent as possible. That way- providers, members, medical directors- whomever these policies are touching- know that we've not only done are best to get it right but to get it right consistently across this organization. This is one of my main goals. I need all of you in clinical practice to keep me grounded; not only in your clinical judgement but you all are also out there seeing patients. You all know what the pain points are with Medicaid. Hopefully, over time my goal is to see fewer and fewer provider concerns. In addition, Inter-rater reliability is about understanding the thought process of interpreting the policy and how a medical director applies that policy and uses the clinical judgement to get to a determination. I want the decisions that come out of Medicaid and the MCOs that provide managed care, to be the same quality as the decisions made by a commercial plan. Dr. Hubbell agreed, stating she spends quite a bit of time training residents on policy rather than medical procedures. Dr. Jagiello- I want to reduce that provider abrasion so that the interpretation of that policy is much more consistent going forward. No other comments.

1. Non-Invasive Prenatal Testing for Aneuploidy Using Cell Free DNA: Recommend:

Open testing to all pregnant women with singleton pregnancy consistent with ACOG recommendation.

Dr. Hubbell: Additional info to add- it's included in the link to the literature here- ACOG in both the New York state Medicaid includes the indication of maternal first or second degree relatives with known aneuploidy would also qualify them to have this testing, I've never had a problem getting this covered under private or commercial policy. Also in relation to Maternal Fetal Medicine, we looked at other options for genetic screening and who it's available to- there's the sequential or the integrated screen, there's the first trimester screen and there's the fetal free cell DNA or amniocentesis. Understanding what's available in our larger, metro areas- the first trimester screen which includes nuchal translucency plus blood testing which is fairly sensitive and accurate at determining these things but that is not available in our rural areas because it requires an ultrasound tech with very specific training, the only options available outside of where these techs are available they have to rely on the integrated screens- blood testing at the first and second trimester which is nowhere near as sensitive at detecting these abnormalities. And typically when the

recommendation that comes back is abnormal, the recommendation is to do the fetal free cell DNA which is a lab draw so it's readily accessible to everyone equally. There is a problem with access to the standard-of care. Dr. Jagiello- I'm going to do some extra research, perform some cross plan comparisons and find the sweet spot of who should be eligible. Dr. Zachary- I think it's antiquated. We have to understand why the age was set at 35, that is where the miscarriage and complications of the amniocentesis occurs- that's the reason why age 35 was set. Dr. Jagiello- In 2015 this is where the research was. They did not favor general screening. Then a year or two later there was ACOG changed its position and recommended that universal screening of all pregnancies (except twins) was a cost effective measure. I will look at the literature and see where it takes us. Dr. Kloepper- in response to a question posed by Dr. Zachary- commercial insurance lines up more with (Amerigroup) they offer it to everybody. Dr. Randleman- it's gotten cheap enough the yield is worth doing, there's no medical reason why we wouldn't offer it to a wider population. Dr. Hubbell- none of the perinatologists that I've worked with will go from an integrated screen to amniocentesis, they just don't do that anymore. They go to the fetal free cell DNA- it's known to be that accurate to then, rather than going to an invasive test that could potentially cause harm. Dr. Jagiello asked ITC, Dr. Benson what they do- Dr. Benson responded- We still require one of the following high risk criteria- abnormal ultrasound, maternal history of child effected with trisomy or the age or a positive result from one of the other quad screens or a parent carrying one of the translocations. They do also look at that is not a multiple gestation and that a cell free DNA test has not been performed yet in this pregnancy. Pre-test counseling, current pregnancy greater than 10 weeks and less than 23 weeks at the time it was drawn. Dr. Jagiello- more to come. CAC committee consensus- we want what Amerigroup is currently using. Voted on recommendation: Open testing to all pregnant women with singleton pregnancy consistent with ACOG recommendation. Dr. Randleman- the recommendations of this board are highly valued and policy usually goes along with it unless there's an absolute compelling reason not to, as opposed to Hawki, which recommendations may or may not be followed.

2. Avelumab (Bavenico): Added "or renal cell carcinoma" to Criteria #1

3. Cerliponase alpha (Brineura): Replaced criteria 1 – 3 with

- Patient is 3 years of age or older AND
- Patient must have a definitive diagnosis of late infantile CLN2 confirmed by deficiency of the lysosomal enzyme tripeptidyl peptidase-1 (TPP1) AND
- Patient has symptomatic disease (e.g., seizures, motor decline, cognitive decline, decreased visual acuity, etc.) AND
- Patient is ambulatory AND
- Patient must not have ventriculoperitoneal shunts AND
- Patient must not have acute intraventricular access device-related complications (e.g., leakage, device failure, or device-related infection) AND
- Patients with a history of bradycardia, conduction disorder, or with structural heart disease must have electrocardiogram (ECG) monitoring performed during the infusion AND
- Baseline documentation of pretreatment motor function/milestones, including but not limited to, the following validated scale: the Motor domain of a Hamburg CLN2 Clinical Rating Scale, etc.
- Initial approval is for 6 months.
- And add Renewal approval criteria:
- Patient continues to meet the criteria above AND
- Absence of unacceptable toxicity from the drug or complications from the device. Examples include the following: intraventricular access device leakage or infection, severe hypersensitivity reaction, severe hypotension; etc. AND
- Patient had a 12-lead ECG evaluation performed within the last 6 months (those with cardiac abnormalities require ECG during each infusion) AND
- Patient has responded to therapy compared to pretreatment baseline with stability/lack of decline in motor function/milestones on validated scale such as the Motor domain of the CLN2 Clinical Rating Scale, etc.
 - Note: decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale
- Renewal approval is for 12 months

4. Durvalumab (Imfinzi): Policy varies from Amerigroup's- indications for treatment of stage 3 non-small cell.
5. Edaravone (Radicava): No recommendations
6. Natalizumab (Tysabri)- Add b. to Criteria #1: highly active disease would allow Tysabri as first line therapy which as defined as in broad terms, highly active MS can include any combination of the following conditions:
 - ☐ Onset with significantly disabling symptoms often related to spinal cord or brainstem/cerebellar lesions
 - ☐ Refractory to relapse suppression, with poor recovery from relapses
 - ☐ Significant recurrent or breakthrough disease over a short period of time
 - ☐ Significant MRI findings (multiple enhancing lesions and/or overall high lesion burden)
 - ☐ Rapid progression to disability
 - ☐ Severity of disease activity must be evaluated based on a combination of:
 - ☐ Clinical presentation (symptoms presentation and severity of disability)
 - ☐ MRI lesion burden (number, size, and location, and degree of change between baseline and follow-up T2/FLAIR scans) and factors such as T1 hypointensities ("black holes"), and brain and spinal cord atrophy
 - ☐ Patient characteristics such as gender, race, and age of onset."
7. Ocrelizumab (Ocrevus): No recommendations
8. Tisagenlecleucel (Kymriah): No recommendations
9. Vivitrol (Naltrexone): Removed 'or narcotic' from Criteria definition after opioid use since all opioids are narcotics.
10. Visual Aids and Vision Therapy: No recommendations
11. Ceiling Track Lifts and/or Electric Patient Lifts: No recommendations
12. Home and Vehicle Modification: No recommendations
13. Mobility Related Device Purchase: Dr. Jagiello will seek assistance from Subject Matter Expert on pediatric DME from ChildServe. Amerigroup doesn't use InterQual but Iowa Total Care (ITC) does. Amerigroup uses Anthem or Amerigroup and then Iowa Code.
14. Power Wheelchair Attendant Controls: No recommendations
15. Colonography: No recommendations
16. Pharmacy ordered/administered vaccines: It will be brought back before the committee in January but won't go into effect until July 31, 2020.
17. Pre-vocational Services: No recommendations
18. Transcranial Magnetic Stimulation: Moving from investigational status to Medical Necessity and move forward with formation of the policy.

19. Cochlear Implant: Built in obsolescence, return to this in January.
20. Hemangioma Removal: No recommendations
21. Nipple Tattooing: No recommendations
22. Panniculectomy: Dr. Jagiello will compare policies
23. CMH LOC- follow up from August meeting, unable to change it due to being subject to Iowa code. We will let Dr. Mandler know.
24. ICF/ID LOC: Will follow up on this in January.
25. Pediatric Skilled Nursing Facility LOC: No recommendations

Adjournment:

Meeting was adjourned to the public. Went to close session.